riverpoint

SEP 2 4 2009

K092059
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510(k) Summary

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or 866 445-4923
Fax Number:	(503) 517-8002
Registration Number:	3006981798
Contact Person:	Douglas Rowley (503) 517-8001
Date of Preparation:	July 1st, 2009

Device Name

Trade Name:	RP Cutting Needle
Common Name:	Biopsy Needle (Disposable)
Classification Name:	Instrument, Biopsy

Device Classification

FDA Class:	2
Product Classification:	876.1075(a) Gastroenterology-Urology Biopsy Instrument, Needle
Code:	KNW
Classification Panel:	Gastroenterology-Urology

Predicate Devices

C.R. Bard®:	Biopty-Cut® Needle; Magnum® Needle
Remington Medical:	MLL Needle; M-Needle
Cook® Medical:	Cook Biopsy Needle

Special Controls

Not applicable for this device

Device Description

The RP Cutting Needle is a sterile, disposable biopsy instrument composed of a stainless steel cannula with a molded plastic hub, and a stainless steel stylet with a notch removed for specimen collection and a molded plastic hub. The cannula and stylet hubs are provided with a spacer attached which is designed to allow for easy insertion of both hubs into a Bard® Magnum® reusable biopsy instrument. The needle is covered with a LDPE sheath for safety.
Needles are available in 14-20 gauge, with lengths between 10 and 25 cm.
The predicate devices listed contain identical or substantially equivalent materials and characteristics as described above.

Intended Use

The RP Cutting Needle is intended to be used by medical professionals with the Bard® Magnum® reusable biopsy instrument for biopsies of soft tissues, such as the liver, lung, kidney or prostate. The RP Cutting Needle is not intended for use in bone.
The RP Cutting Needle is provided sterile as a single use device.

Safety and Effectiveness

The RP Cutting needle is designed and manufactured to be substantially equivalent to the predicate devices listed below for safety and effectiveness. All materials used were selected based on known biocompatibility and established histories of use in the medical device industry for non-implantable devices, and are identical or substantially equivalent to the materials used in the predicate devices listed.
The RP Cutting Needle has been designed to have the same general shape, size and method of function as the predicate devices. Dimensional, functional and quality verifications, along with material certification has confirmed that the RP Cutting Needle is substantially equivalent to the predicate devices in size, shape, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 24 2009

Mr. Doug Rowley
RA/QA Manager
Riverpoint Medical
825 NE 25th Avenue
PORTLAND OR 97232

Re: K092059
Trade/Device Name: RP Cutting Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: July 1, 2009
Received: July 7, 2009

Dear Mr. Rowley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number: K092059

Device Name: RP Cutting Needle

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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